

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D2034115	(X3) Date Survey Completed 04/30/2018
Name of Provider or Supplier Medicare Express-North Charleston Llc	Street Address, City, State 1115 Savannah Hwy, Charleston, SC	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5447	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: During an onsite recertification survey on 4/30/2018, based on hematology data log review and testing personnel interview, the laboratory failed to perform and document at least two levels of acceptable hematology quality control (QC) before patient testing on 9 random test days reviewed from 2017. Findings include: 1. Review of the hematology data log revealed that patient complete blood count (CBC) testing was performed on the following days before having two levels of acceptable controls: a. 4/14/2017--hemoglobin (Hgb) out of range on normal and high controls; 4 patients tested b. 4/17/2017--Hgb out of range on normal and high controls; 5 patients tested c. 4/20/2017--Hgb out of range on normal and high controls; 2 patients tested d. 4/29/2017--Hgb out of range on normal and high controls; 3 patients tested e. 5/5/2017--Hgb out of range on normal and high controls; 4 patients tested f. 5/10/2017--Hgb out of range on normal and high controls; 6 patients tested g. 7/18/2017--Hgb out of range on normal and high controls; 6 patients tested h. 7/25/2017--red blood count (RBC) out of range on low and normal controls; Hgb out of range on normal and high controls; 5 patients tested i. 8/28/2017--Hgb out of range on normal and high controls; 8 patients tested 2. Testing personnel confirmed during an interview on 4/30/2018 at 11:00 am that the laboratory failed to perform and document at least two levels of acceptable hematology QC on these dates. THIS IS A REPEAT DEFICIENCY</p>
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

During an onsite recertification survey on 4/30/2018, based on quality control review and lack of documentation, the laboratory failed to establish and follow written policies and procedures to monitor, assess, and correct problems associated with unacceptable quality control testing (see D5447).